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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,383	EAGLAND ET AL.	
	Examiner	Art Unit	
	MICHAEL CATINA	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/20/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-23,29,31 and 37-39* is/are pending in the application.

5a) Of the above claim(s) *24-28,30,32-36* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-23,29,31 and 37-39* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/22/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed on June 21, 2006. **Claims 24-28, 30, 32-36** are cancelled. **Claims 37-39** are new. **Claims 1-23, 29, 31 and 37-39** are currently pending and an action on the merits is as follows.

Claim Objections

1. **Claim 22** objected to because of the following informalities: "to any claim 2" appears as if it should read "to claim 2". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 7** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the claim is dependent on claim 1 or claim 2. For the purposes of examination it is taken to be dependent on claim 2.

4. **Claims 10 and 29** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding **claim 10**, it is unclear what is referred to as the second and third polymeric material and where either compound originates since there is no mention of a first polymeric material is the proceeding claims on which claim 10 is dependent. It is also unclear what the relationship of the cross-linking is. For the purpose of examination it is taken to mean that a second material is formed from the cross-linking of another, or third material.

6. Regarding **claim 29**, it is also unclear what is being referred to as the third polymeric compound when there is not mention of a first or second polymeric compound.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by Lawrence et al. US 5,897,834 **("Lawrence")**

9. Regarding **claim 1**, Lawrence discloses a method of assessing the pH of a substrate or environment, the method comprising contacting the substrate with a test material or introducing the test material into an environment, wherein said test material is arranged to change color according to pH (see [abstract][C1 L10-17] wherein the device is used for testing pH in aqueous fluid. [C3 L40-65] wherein the pH is indicated by a colorimetric change. Wherein the substrate is the sample being tested or the swab on which it is carried).

10. **Claims 1,2,4,9,20-22** are rejected under 35 U.S.C. 102(b) as being anticipated by Bonstein et al. US 6,562,297 ("Bonstein")

11. Regarding **claim 1**, Bonstein discloses a method of assessing the pH of a substrate or environment, the method comprising contacting the substrate with a test material (pH sensor **10**) or introducing the test material into an environment, wherein said test material is arranged to change color according to pH ([C4 L51-67] wherein the pH is indicated by color change of the test strip incorporated on the device. [C8 L30-62] wherein the pH sensor or strip is incorporated into a tampon or hygienic pad which would by the nature of its use be arranged to contact a substrate or be introduced into an environment, i.e. the vagina)

12. Regarding **claim 2**, Bonstein discloses wherein said substrate or environment is a tissue of a human or animal body, and said test material is at least a part of a dressing having a main surface arranged to contact a said tissue wherein the test material is arranged to contact a first area of a said tissue ([C4 L14-16][C8 L30-62] wherein the pH sensor strip 10 is arranged on the surface of the device, tampon or sanitary napkin either of which could be a dressing, and is arranged to contact the tissue of the patient) and the test material is such that is arranged to change color over at least 50% of the area of the first area so that the pH of individual elements of at least 50% of said first area can be monitored ([C4 L29-36][C7 L50-59] wherein the pH sensor strip is embedded entirely with an indicator therefore changes color over its entirety therefore at least 50% and indicates the condition of the entire area it contacts)

13. Regarding **claim 4**, Bonstein discloses wherein said material comprises a carrier means and an indicator means arranged to change color according to pH ([C4 L29-34] wherein a pH indicator is immobilizing a pH indicator on a hydrophilic membrane, carrier)

14. Regarding **claim 9**, Bonstein discloses wherein said test material is in sheet form and is arranged to change color according to pH at first, second, third and fourth positions thereon, wherein the ratio of the area defined between said four positions to the area of the main surface of the sheet is at least 0.5. ([FIG 1-3] wherein the pH sensing area 10 is a sheet or strip and

since it is covering a surface area it has at least a first, second third and fourth sensing area in that different parts of the sensor could react separately. The pH indicator 10 has a surface area therefore it will change color dependant on what various parts of its surface touch thereby it has different zones or positions that indicate pH by color change)

15. Regarding **claim 20 and 21**, Bonstein discloses wherein said test material is part of a dressing for the human or animal body and said test material is arranged to provide a pH map of a substrate which it contacts ([C4 L14-16][C8 L30-62][FIG 1-3] wherein the pH material is incorporated into a hygienic pad, which can be considered a dressing and the pH material itself is arranged in a strip that can by the nature of it having a reasonable surface area will map the pH of what it contacts since the material will change pH according to what it touches).

16. Regarding **claim 22**, Bonstein discloses wherein said test material is arranged, by virtue of it being transparent, to allow color changes to be observed with the test material in situ ([C8 L30-63] wherein layer 18 should be transparent in order to allow the user to view the pH sensor).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. **Claims 2-4,6,7,16,17,20,23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawrence et al. US 5,897,834 ("Lawrence") in view of Perrault et al. US 4,717,378 ("Perrault")

19. Regarding **claim 2**, Lawrence discloses all claimed elements including wherein 50% of the area of the device is used as a color indicator (see [FIG 4a]) Lawrence does not specifically discloses "wherein said substrate or environment is a tissue of a human or animal body, and said test material is at least a part of a dressing having a main surface arranged to contact a said tissue wherein the test material is arranged to contact a first area of a said tissue". Perrault teaches a method for indicating pH using hydrogel as part of a dressing or bandage wherein the hydrogel changes color over its entirety, so at least 50%, and contacts a tissue of a subject (see [C1 L58-68][C2 L26-42] wherein the gel is part of the working surface or contacting surface of a biomedical device, such a device being a wound dressing or large area bandage). Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Lawrence with the teachings of Perrault in order to

test pH of a wound since the device of Lawrence can be used to test blood pH or any aqueous solution (see [C9 L40-43])

20. Regarding **claim 3**, in the modified method of Lawrence and Perrault, Perrault discloses wherein said test material is a hydrogel (see [C1 L44-55][C4 L10-64] wherein the invention relates to hydrogels on skin contacting surfaces of biomedical devices, i.e. wound bandages). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Lawrence with the teachings of Perrault since Lawrence discloses using a hydrophilic and porous material for the test material (C6 L60 to C7 L17) and hydrogels are hydrophilic porous materials.

21. Regarding **claim 4**, in the modified method of Lawrence and Perrault, Lawrence discloses wherein said material comprises a carrier means and an indicator means arranged to change color according to pH ([C7 L31-51] wherein the pH indicator and the polymer, carrier, form a solid thin layer referred to as the pH indicator lamina where the indicator changes color according to pH).

22. Regarding **claim 6**, in the modified method of Lawrence and Perrault, Lawrence discloses wherein said indicator means is impregnated in said carrier means and trapped therein in a matrix defined by said carrier means (see [C3 L40-65] wherein the indicator is immobilized in the solid polymer matrix).

23. Regarding **claim 7**, in the modified device of Lawrence and Perrault, Lawrence discloses wherein said test material includes at least 0.01 wt% and

less than 3 wt% of said indicator means (see [C7 L27-28] wherein the indicator ideally constitutes .1% to .6% by weight which falls within the claimed range).

24. Regarding **claim 16**, in the modified method of Lawrence and Perrault, Lawrence discloses wherein said test material comprises a carrier means and an indicator means which is trapped within a matrix defined by the carrier means wherein said indicator means is not covalently bonded to the carrier means ([C3 L44-65][C17 L58-62] wherein the indicator is immobilized in the hydrophilic matrix, carrier).

25. Regarding **claim 17**, in the modified method of Lawrence and Perrault, Lawrence teaches comparing the visual appearance of the test material with a reference means([C11 L49-54] wherein a portion or third indicator should be protected in order to serve as a negative reference means).

26. Regarding **claim 20**, Lawrence discloses all claimed elements however "wherein said test material is part of a dressing for the human or animal body and said test material is arranged to provide a pH map of a substrate which it contacts" is not specifically disclosed. Perrault however teaches a incorporating a hydrogel into a wound dressing is known in the art ([C1 L19-27][C2 L26-31] wherein the gel is incorporated into a wound dressing for a human patient and the gel by the nature of the fact that it covers an area, indicated by the mention that a film can be placed over a section in order to preserve pH for comparison, will provide map the pH of what it contacts over the area of its surface). Therefore it would have been obvious to one of ordinary skill in the art at the

time of invention to modify the device of Lawrence with the teachings of Perrault since Lawrence discloses using a hydrophilic and porous material for the test material (C6 L60 to C7 L17) and hydrogels are hydrophilic porous materials.

27. Regarding **claim 23**, Lawrence discloses test material is used to asses the pH of part of a human or animal body ([abstract] wherein the device is for assessing biological fluids). However "test material includes securement means for securing it relative to a said substrate" is not specifically disclosed. However Perrault does teach that pH indicating hydrogels can be incorporated into bandages ([C1 L19-27][C2 L26-31] wherein the hydrogels are incorporated into large area dressings and bandages, which have securement means in order to attach to the wound or body). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Lawrence with the teachings of Perrault since Lawrence discloses using a hydrophilic and porous material for the test material (C6 L60 to C7 L17) and hydrogels are hydrophilic porous materials.

1. **Claims 10-13, 15 and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawrence et al. US 5,897,834 ("Lawrence") and Perrault et

al. US 4,717,378 ("Perrault") further in view of Eagland et al. GB 2,317,895 A ("Eagland")

2. Regarding **claim 10**, the modified method of Lawrence and Perrault disclose all claimed elements however do not specifically disclose wherein said test material includes a second polymeric material comprising a third polymeric material which is cross-linked by a cross-linking means. Eagland teaches polymeric hydrogels using a cross-linked polymeric material ([P6 L21 to P7 L14][P8 L4-26][P18 L17] wherein according to a fifth aspect of the invention a gel is formed from a second polymeric material, which would be the third polymeric material, is mixed with a first polymeric material, compounds IV and I which are a cross-linking means, forming a new cross-linked polymer, the second polymeric material of the claim). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Lawrence and Perrault with the teachings of Eagland in order to have a hydrogel that is insoluble in aqueous solution and shows limited swelling which would be favorable in applications with biological fluids ([P17 L23-31]).

3. Regarding **claim 11 and 12**, the modified method of Lawrence and Perrault disclose all claimed elements however do not specifically disclose wherein said the third polymeric material is selected from optionally substituted polyvinyl alcohol, polyvinyl acetate, polyalkalene glycols and collagen. Eagland teaches using polyvinyl alcohol as the polymer to be cross-linked ([P6 L21 to P7 L14][P8 L4-26] wherein according to the third aspect of

the method, the formulation to be turned into a hydrogel according to the fifth aspect can included as the polvinylalcohol, polyvinylacetate, polyalkalene glycol and collagen). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Lawrence and Perrault with the teachings of Eagland in order to have a hydrogel that is insoluble in aqueous solution and shows limited swelling which would be favorable in applications with biological fluids ([P17 L23-31]).

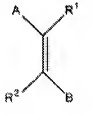
4. Regarding **claim 13**, the modified method of Lawrence and Perrault disclose all claimed elements however do not specifically disclose wherein said second polymeric material includes cross-linked polyvinyl alcohol or a copolymer thereof. Eagland teaches using polyvinyl alcohol as the polymer to be cross-linked ([P6 L21 to P7 L14][P8 L4-26][P18 L17] wherein according to the third aspect of the method, the formulation to be turned into a hydrogel in the fifth aspect can included as the polvinylalcohol, polyvinylacetate, polyalkalene glycol and collagen). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Lawrence and Perrault with the teachings of Eagland in order to have a hydrogel that is insoluble in aqueous solution and shows limited swelling which would be favorable in applications with biological fluids ([P17 L23-31]).

5. Regarding **claim 15**, the modified method of Lawrence and Perrault disclose all claimed elements however do not specifically disclose wherein said cross- linking means comprises:

(a) a first polymeric material having a repeat unit of formula

wherein A and B are the same or different, are selected from optionally-substituted aromatic and heteroaromatic groups and at least one comprises a relatively polar atom or group and R1 and R2 independently comprise relatively non-polar atoms or groups; or

(b) a first polymeric material prepared or preparable by providing a compound of general formula



wherein A, B, R1 and R2 are as described above, in an aqueous solvent and causing the groups C=C in said compound to react with one another to form said first polymeric material. Eagland teaches using these structures as cross-linking means ([P1 L24 to P2 L7][P3 L6-16][P6 L10-20] wherein the A,B,R1 and R2 are selected from optionally-substituted aromatic and heteroaromatic groups and at least one comprises a relatively polar atom or group and R1 and R2 independently comprise relatively non-polar atoms or groups. [P6 L21 to P7

L14][P8 L4-26][P18 L17] wherein according to the third aspect of the method, the formulation to be turned into a hydrogel in the fifth aspect is a polvinylalcohol and mixed with a first polymer, structures I and IV, in order to form the polyvinyl cross-link gel). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Lawrence and Perrault with the teachings of Eagland in order to have a hydrogel that is insoluble in aqueous solution and shows limited swelling which would be favorable in applications with biological fluids ([P17 L23-31]).

6. Regarding **claim 29**, in the modified method of Lawrence and Perrault, Lawrence discloses a method of assessing pH of a substrate or environment, the method comprising contacting the substrate with a test material or introducing the test material into an environment (see [abstract][C1 L10-17] wherein the device is used for testing pH in aqueous fluid. Substrate being the fluid sample and swab) however "wherein said test material includes a third polymeric material, cross-linked by a cross-linking means, wherein said cross-linking means incorporates aromatic or hetero-aromatic groups" is not specifically disclosed. Eagland teaches using polyvinyl alcohol as the polymer to be cross-linked ([P1 L24 to P2 L7][P3 L6-16][P6 L10-20] wherein the A,B,R1 and R2 are selected from optionally-substituted aromatic and heteroaromatic groups and at least one comprises a relatively polar atom or group and R1 and R2 independently comprise relatively non-polar atoms or groups. [P6 L21 to P7 L14][P8 L4-26][P18 L17] wherein according to the third aspect of the method,

the formulation to be turned into a hydrogel in the fifth aspect is a polvinylalcohol and mixed with a first polymer, structures I and IV, in order to form the polyvinyl cross-link gel). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Lawrence and Perrault with the teachings of Eagland in order to have a hydrogel that is insoluble in aqueous solution and shows limited swelling which would be favorable in applications with biological fluids ([P17 L23-31]).

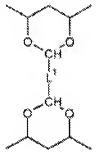
7. **Claim 5 and 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonstein et al. US 6,562,297 ("Bonstein") in view of Adams et al. US 6,391,626 ("Adams")

8. Regarding **claim 5**, Bonstein discloses all claimed elements however "wherein said carrier means and said indicator means are covalently bonded to one another" is not specifically disclosed. Adams however teaches a pH testing media wherein the indicator means is covalently bonded to its carrier ([C3 L66 to C4 L4] wherein the pH indicator is covalently bonded to the ballast, carrier). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify Bonstein by the teachings of Adams in order to prevent the pH indicator from bleeding out of the test material and for more accurate detection of pH by zones ([C4 L27-39]).

9. Regarding **claim 8**, Bonstein discloses all elements including the carrier and pH indicator dye being synthetic (see [C7 L7-26]) however "wherein said carrier means comprises a natural or synthetic polymer or a residue thereof in the event that said indicator means is covalently bonded to the carrier means; and said indicator means comprises a natural or synthetic material or a residue thereof in the event said indicator means is covalently bonded to said carrier means" is not specifically disclose. Adams teaches a pH testing material wherein the carrier means and indicator are synthetic polymers and are covalently bonded ([C3 L13 to C4 L18] wherein the carrier means is of either natural or synthetic polymers: cellulose, polyvinyl alcohol etc. and the pH indicator listed are synthetic polymers). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify Bonstein by the teachings of Adams in order to prevent the pH indicator from bleeding out of the test material and for more accurate detection of pH by zones ([C4 L27-39]).

10. **Claim 14** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lawrence et al. US 5,897,834 ("Lawrence") and Perrault et al. US 4,717,378 ("Perrault") further in view of Eagland et al. GB 2,317,895 A ("Eagland") and Hofeditz et al. US 4,552,138 ("Hofeditz")

11. Regarding **claim 14**, the modified method of Lawrence and Perrault further modified by Eagland discloses all claimed elements however, "wherein said second polymeric material includes a moiety of formula I:



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wherein L^1 is a residue of said cross-linking means" is not specifically disclosed. Hofeditz teaches that hydrogels with such a structure are known in the art ([C1 L26-34] wherein it is known to use glutaraldehyde, referred to as glutardialhyde, to cross-link polyvinyl alcohol which would result in such a structure). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Lawrence, Perrault and Eagland with the teachings of Hofeditz since it is known to use hydrogels of this type to treat wounds and would allow the device to be used in treating wounds ([C1 L31])

12. **Claims 18 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonstein et al. US 6,562,297 ("Bonstein") in view of Alvarez US 4,813,942 ("Alvarez")

13. Regarding **claims 18 and 19**, Bonstein discloses all claimed elements however "assessing the pH of a tissue of the human or animal body and a subsequent treatment of said body is selected in dependence upon the pH assessed" is not disclosed. Alvarez however teaches a wound dressing with a pH indicator in which the pH is assessed in order to further the treatment ([C3 L52-64][C4 L40-47] wherein the pH of the dressing assessed and the debridement bandage is removed when an appropriate pH is reached and then a second dressing is applied in order to promote regeneration). Therefore it would have been obvious to one of ordinary skill in the art to modify Bonstein by the teachings of Alvarez in order to use the absorbent dressing disclosed by Bonstein as a bandage and to assess the wound and treat it according to the stages of healing (see [C1 L45-66]).

14. **Claims 31 and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Perrault et al. US 4,717,378 ("Perrault") in view of Beal et al. US 2,402,981 ("Beal")

15. Regarding **claim 31**, Perrault discloses a material comprising a carrier means in a form of a hydrogel and an indicator means arranged to change color according to pH ([C1 L58-68] wherein the device has a hydrogel with a pH indicator therein). Perrault however does not discloses a package which contains a test material in a sterile environment wherein said test material, releasing said test material. Beal teaches packaging bandages in sterile envelopes ([C1 L1-32][] wherein device is for the packaging of surgical dressings specifically dressing embedded with material. [C3 L3-5] wherein the envelope is sterilized in an autoclave and the envelope is protected from contaminates. [C4 L17-41] wherein the dressing can be withdrawn from the packaging). Therefore it would have been obvious to modify Perrault with the teachings of Beal as Perrault discloses incorporating hydrogel into large area bandages (see [C1 L16-25][C2 L26-36]) and it would be obvious to include packaging to keep these bandages sterile.

16. Regarding **claim 37**, Perrault discloses the use of the test material in assessing the pH of a substrate or environment ([C1 L58-68] wherein the pH indicator shows the pH of the hydrogel based on its exposure to open air, this exposure to air being an environment).

17. **Claims 38 and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonstein et al. US 6,562,297 ("Bonstein") in view of Perrault et al. US 4,717,378 ("Perrault").

18. Regarding **claim 38**, Bonstein discloses a method of assessing the pH of a tissue of a human or animal body, the method comprising contacting said tissue with a test material ([FIG1-3][C8 L30-62] wherein the test material is situated on a hygienic pad or tampon and thus contacts a tissue), wherein said test material is in sheet form and is arranged to change color independently according to pH at first, second, third and fourth positions thereon, wherein the ratio of the area defined between said first, second, third and fourth positions to the area of a major surface of said test material is at least 0.5 ([FIG 1-3] wherein pH sensor 10 is flat and arranged such that its surface area allows for color change in first, second, third and fourth positions since it changes based on the pH of what it contacts and has a sufficient area to allow for different readings. The sensor, test material, also changes color of its entire surface so it is at least .5), wherein said test material is arranged to display a color indicative of the pH at a first position which it contacts and to display a color indicative of the pH at another position it contacts so that a pH map of a tissue contacted by said test material can be defined ([FIG1-3] the pH sensor is arranged in such a way that it also for pH mapping. It has a surface area that would allow it to change color differently over its surface depending on what it contacts, i.e. if part of the sensor 10 contacted a pH lowering surface and the

other end contacted a surface with a high pH it would be easily discernable). Bonstein however does not specifically disclose "a hydrogel comprising a carrier means and an indicator means arranged to change color according to pH". Perrault discloses a hydrogel with a pH indicator incorporated into a dressing or bandage ([C1 L19-36][C1 L58 to C2 L8][C2 L26-36] wherein a pH indicator is mixed with a hydrogel and can be used as part of a wound dressing or bandage). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify Bonstein by the teachings of Perrault since Bonstein discloses using a synthetic hydrophilic membrane of any suitable polymer (see [C7 L16-17]) for the pH indicator carrier means and hydrogels, which are hydrophilic membranes, as taught by Perrault have been used in biomedical devices and can have an incorporated pH indicator.

19. Regarding **claim 39**, wherein said test material is in sheet form ([FIG 1-3][C8 L30-63] wherein the device is arranged as absorbent sheets and the indicator is a sheet of a hydrophilic membrane) and is arranged to change color independently according to pH at first, second, third and fourth positions thereon, wherein the ratio of the area defined between said first, second, third and fourth positions to the area of a major surface of said test material is at least 0.5 ([FIG 1-3] wherein pH sensor 10 is flat and arranged such that its surface area allows for color change in first, second, third and fourth positions since it changes based on the pH of what it contacts and has a sufficient area to allow for different readings. The sensor, test material, also changes color of

its entire surface so it is at least .5) wherein said test material is arranged to display a color indicative of the pH at a first position which it contacts in use and to display a color indicative of the pH at another position it contacts in use so that a pH map of a tissue contacted in use by said test material can be defined ([FIG1-3] the pH sensor is arranged in such a way that it also for pH mapping. It has a surface area that would allow it to change color differently over its surface depending on what it contacts, i.e. if part of the sensor 10 contacted a pH lowering surface and the other end contacted a surface with a high pH it would be easily discernable). Bonstein however does not specifically disclose "a hydrogel comprising a carrier means and an indicator means arranged to change color according to pH". Perrault discloses a hydrogel with a pH indicator incorporated into a dressing or bandage ([C1 L19-36][C1 L58 to C2 L8][C2 L26-36] wherein a pH indicator is mixed with a hydrogel and can be used as part of a wound dressing or bandage). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify Bonstein by the teachings of Perrault since Bonstein discloses using a synthetic hydrophilic membrane of any suitable polymer (see [C7 L16-17]) for the pH indicator carrier means and hydrogels, which are hydrophilic membranes, as taught by Perrault have been used in biomedical devices and can have an incorporated pH indicator.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL CATINA whose telephone number is (571)270-5951. The examiner can normally be reached on M-F: 7:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Miranda Le can be reached on 571-272-4112. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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